

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

UNITED STATES OF AMERICA, et al.,  
ex rel. CALEB HERNANDEZ and JASON  
WHALEY, Relators,

*Plaintiffs,*

v.

TEAM HEALTH HOLDINGS INC., et al.,

*Defendants.*

CASE NO. 2:16-cv-00432-JRG

**DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY IN SUPPORT OF  
MOTION FOR SUMMARY JUDGMENT (DKT. 172) AND OTHER MOTIONS**

Defendants respectfully submit this Notice of Supplemental Authority to advise the Court of a new regulation finalized by the Department of Health and Human Services (“HHS”) on December 3, 2020, titled “Department of Health and Human Services Good Guidance Practices” (“Good Guidance Practices Regulation”).<sup>1</sup> Defendants also advise the Court of HHS’s accompanying commentary and advisory opinion.<sup>2</sup> These new authorities bear on at least the following pending motions that are likely to be argued at the upcoming Pretrial Conference:

- Defendants’ Motion for Summary Judgment (Dkt. 172);
- Defendants’ Motion to Dismiss Relators’ Third Amended Complaint (Dkt. 181);
- Defendants’ Motion to Exclude the Opinion Testimony of Relators’ Designated Experts Kristen Folding and Bruce Wapen (Dkt. 165); and
- Defendants’ pending Motion in Limine Number 6 (Dkt. 240 at pp.5-6)

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<sup>1</sup> 45 CFR Part 1; *see* 85 Fed. Reg. 78770–78787 (Dec. 7, 2020 publication of final rule with HHS commentary) (attached as **Ex. A**). The new regulation is codified at 45 C.F.R. §§ 1.1–1.5.

<sup>2</sup> HHS Office of General Counsel Advisory Op. 20-05, “On Implementing *Allina*” (Dec. 3, 2020) (attached as **Ex. B**).

The new authorities bear on these pending motions in at least the following ways:

Consistent with the Supreme Court's ruling in *Azar v. Allina Health Services*, 139 S.Ct. 1805 (2019), section 1.3 of the regulation makes clear that HHS guidance documents, such as the Medicare Claims Processing Manual ("Manual" or "MCPM") and similar CMS manuals, do not have the force and effect of law and therefore cannot be used in HHS (or relators who stand in the shoes of HHS) in enforcement actions:

*A: Guidance documents.*

(1) Under the Administrative Procedure Act, the Department may not issue any guidance document that establishes a legal obligation that is not reflected in a duly enacted statute or in a regulation lawfully promulgated under a statute.

(2) *The Department may not use any guidance document for purposes of requiring a person or entity outside the Department to take any action, or refrain from taking any action, beyond what is required by the terms of an applicable statute or regulation.*

(3) Each guidance document issued by the Department must:

(i) Identify itself as "guidance" (by using the term "guidance") and include the following language, unless the guidance is authorized by law to be binding: "*The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract.* This document is intended only to provide clarity to the public regarding existing requirements under the law." . . .

45 C.F.R. § 1.3; Ex. A, 85 Fed. Reg. at 78785–78786 (emphasis added).

Although the regulation does allow for enforcement of guidance documents to the extent they are "specifically incorporated into a contract," the accompanying commentary from HHS makes clear that contractual compliance certifications do not transform guidance documents into binding legal requirements unless they specifically reference a particular guidance document:

If the government intends for a guidance document incorporated into a contract by reference to have independent legal basis, *the government must make that intention clear through unambiguous language*. For example, if a contract states that Medicare Advantage organizations must operate "in compliance with the requirements of this contract and applicable Federal statutes, regulations, and

policies (e.g., policies as described in the Call Letter, Medicare Managed Care Manual, etc.),” the signatory must comply with CMS call letters and the Medicare Managed Care Manual, because these sub-regulatory materials are specifically referenced in the contract. However, the contract does not make compliance with any other sub-regulatory guidance issued by HHS legally binding.

85 Fed. Reg. at 78779 (emphasis added). For the Court’s reference, the form at issue in this case is CMS Form 1500. Ex 160 to Rels.’ MSJ Resp. (Dkt. 190), p.2.

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In conjunction with the final publication of the new regulation, on December 3, 2020 the HHS Office of General Counsel (“OGC”) released an advisory opinion “on implementing *Allina*.” *See* Ex. B, Implementing *Allina*, Advisory Op. 20-05 (Dec. 3, 2020). The advisory opinion explains the standard that HHS will follow in determining whether a particular alleged violation rests on guidance that is invalid under *Allina*:

The critical question is whether the violation of the Medicare rule could be shown absent the guidance document. If the answer is no, then the guidance document establishes a norm and, under *Allina*, is invalid unless issued through notice-and-comment rulemaking. However, *Allina* does not preclude CMS from enforcing provisions in its contracts or agreements where those provisions, even if originally issued in the form of a guidance document, are expressly and specifically referenced as an obligation of the party to the contract or agreement.

*Id.* at 2.

\* \* \*

Finally, we note for the Court that section 1.5 of the Good Guidance Practices Regulation establishes a procedure for interested parties to petition HHS to withdraw any guidance document that imposes binding obligations beyond those required by the terms of applicable statutes and/or regulations. 45 C.F.R. § 1.5(a)(1). Shortly after the filing of this Notice, Defendants intend to file a petition with HHS seeking the withdrawal of the relevant Manual provisions relied on in this case. Per the regulation, a decision on that request must be rendered no later than 90 business days

after receipt of the petition (unless that time is extended for enumerated reasons). The Court need not wait for that to occur, however, before it rules on the pending motions listed above.

Dated: January 8, 2021

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 8<sup>th</sup> day of January, 2021, a true and complete copy of the foregoing document was served upon all counsel of record via the Courts CM/ECF.

/s/Eric H. Findlay  
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